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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,598	12/12/2003	Scott Freeberg	279.441US1	1744

21186 7590 07/17/2006

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EXAMINER	
KRAMER, NICOLE R	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 07/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

E

Office Action Summary	Application No.	Applicant(s)	
	10/735,598	FREEBERG, SCOTT	
	Examiner	Art Unit	
	Nicole R. Kramer	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10 and 12-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 12-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-10 and 12-20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6 and 20 of U.S. Patent Application Publication 2004/0049237 ("Larson et al.") in view of WO 00/78391 ("Salo et al'), which corresponds to U.S. Patent No. 6,278,894. For convenience purposes, Examiner's citations to Salo et al. refer to citations in the corresponding U.S. Patent document.

Larson et al. claims a minute ventilation sensing device comprising excitation current electrodes, an exciter, voltage sense electrodes, sampling circuitry, circuitry for

detecting noise when no excitation current is supplied, a demodulator, circuitry for filtering the demodulated voltage sense signal into a ventilation band to thereby generate a ventilation signal, and circuitry for deriving a signal proportional to minute ventilation from the ventilation signal. As recited in claim 6 of Larson et al., the voltage sense signals are further filtered into the ventilation band in order to detect a noise level during a noise detection operation. Larson et al. fails to claim a switch matrix with the capability of switching between different electrode configurations for use as voltage sense electrodes, and circuitry for operating the switch matrix to select a configuration of voltage sense electrodes for use by the device that result in the lowest average noise level. Salo et al. teaches a cardiac rhythm management device which teaches a switch matrix (42; see col. 4, lines 15-33) for switching between different electrode configurations for use as voltage sense electrodes in order to select combinations of electrodes with improved signal-to-noise ratios, thereby significantly improving the quality of the impedance measurement (see, for example, col. 3, lines 3-5 and col. 6, lines 5-11). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the claimed device/method of Larson et al. to include a switch matrix for switching between different electrode configurations for use as voltage sense electrodes as taught by Salo et al. in order to select combinations of electrodes with improved signal-to-noise ratios, thereby significantly improving the quality of the impedance measurement. Selection of an electrode combination having an improved signal-to-noise ratio would significantly improve the quality and reliability of the MV

information, and thus allow the cardiac rhythm management device of Larson et al. to continuously deliver appropriate CRM therapy.

With respect to claims 2, 3, 14, and 15, selection of a configuration of voltage sense electrodes for use by the device that results in the highest signal-to-noise ratio would be obvious to one having ordinary skill in the art in order to enhance the quality and reliability of the MV information as much as possible.

Further with respect to claims 3, 7, 15, and 19, Salo et al. teaches that the switch matrix has the capability of selecting one or several electrodes to function either as a drive electrode or a sense electrode (see col. 4, lines 15-20).

With respect to claims 4-5 and 16-17, Larson et al. teaches that it is well known in the art to utilize a header as an indifferent electrode (see paragraph 0023).

With respect to claims 6 and 18, Salo et al. teaches that the plurality of selectable voltage sense and excitation current electrodes include the tip and ring electrodes of a plurality of sensing/pacing leads (leads 12, 14, and 15).

With respect to claims 8, 10, and 20, Larson et al. claims that the circuitry for demodulating the voltage sense signal samples generates a weighted average of the voltage sense signal samples (see claims 2 and 16).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-20 rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,161,042 ("Hartley et al.") in view of WO 00/78391 ("Salo et al'), which corresponds to U.S. Patent No. 6,278,894. For convenience purposes, Examiner's citations to Salo et al. refer to citations in the corresponding U.S. Patent document.

Hartley et al. discloses a cardiac rhythm management device that detects transthoracic impedance, extracts minute ventilation information therefrom, and adjusts a delivery rate of the pacing therapy according to the extracted minute ventilation information. More specifically, the device includes an exciter coupled to a thorax of a patient for repeatedly delivering a multiphase stimulus thereto, a signal processor for obtaining transthoracic impedance information responsive to the stimuli, a demodulator that includes sampling elements for demodulating the impedance in response to different phases of the stimulus, a controller for adjusting the rate of delivery of pacing therapy based on the transthoracic impedance information, and a therapy circuit for delivering therapy to the heart of a patient (see col. 3, line 60 - col. 4, line 6). A minute ventilation signal is derived from the impedance signal for indicating a metabolic need for an increased heart rate (see col., 6, lines 30-50). The device ignores the MV information when a noise-measurement exceeds a threshold (see Abstract). More specifically, the demodulator 415 provides the noise sensing mode or operation for detecting noise when no excitation current is supplied and for computing an average noise level (see col. 12, lines 11-48). If the detected noise is above a threshold value, subsequent circuits ignore the output of the demodulator until the detected noise falls

below the threshold value (see col. 12, lines 11--48). Hartley et al. discloses that the gain of the demodulator 415 may be increased during the noise sensing mode in order to provide for more sensitive noise detection (see col. 12, lines 25-33). In view of the disclosure that the demodulator 415 provides a voltage gain for the ventilation band during the noise sensing mode of operation, Examiner considers Hartley et al. to disclose filtering the voltage sensed signal when no excitation current is supplied into the ventilation band since such gain necessarily results in allowing only a particular range of voltages to be analyzed.

In addition, with respect to device claims 1-10 and 12, Examiner notes that the device of Hartley et al. has the capability of filtering voltage sense signals via demodulator 415 (see col. 11, lines 13-33) and bandpass filter 420 (see col. 12, line 50 - col. 13, line 13). A recitation of the intended use of the claimed invention (for example, the intended use of the circuitry for detecting noise when no excitation is supplied) must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Since the device of Hartley et al. is capable of filtering the voltage sense signals during normal operation, Examiner considers the device also capable of filtering such signals during the noise sensing mode of operation described at col. 12, lines 11-48.

Hartley et al. fails to disclose a switch matrix with the capability of switching between different electrode configurations for use as voltage sense electrodes, and circuitry for operating the switch matrix to select a configuration of voltage sense

electrodes for use by the device that result in the lowest average noise level. Salo et al. teaches a cardiac rhythm management device which teaches a switch matrix (42; see col. 4, lines 15-33) for switching between different electrode configurations for use as voltage sense electrodes in order to select combinations of electrodes with improved signal-to-noise ratios, thereby significantly improving the quality of the impedance measurement (see, for example, col. 3, lines 3-5 and col. 6, lines 5-11). In addition to or rather than ignoring the MV information when the detected noise exceeds a threshold value, it would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the device of Hartley et al. to include a switch matrix for switching between different electrode configurations for use as voltage sense electrodes as taught by Salo et al. in order to select combinations of electrodes with improved signal-to-noise ratios, thereby significantly improving the quality of the impedance measurement. Selection of an electrode combination having an improved signal-to-noise ratio would significantly improve the quality and reliability of the MV information, and thus allow the cardiac rhythm management device of Hartley et al. to continuously deliver appropriate CRM therapy.

With respect to claims 2, 3, 14, and 15, selection of a configuration of voltage sense electrodes for use by the device that results in the highest signal-to-noise ratio would be obvious to one having ordinary skill in the art in order to enhance the quality and reliability of the MV information as much as possible.

Further with respect to claims 3, 7, 15, and 19, Salo et al. teaches that the switch matrix has the capability of selecting one or several electrodes to function either as a drive electrode or a sense electrode (see col. 4, lines 15-20).

With respect to claims 4-5 and 16-17, Hartley et al. discloses that various electrode configurations, including that header 140 may include an indifferent electrode (see col. 5, line 57 - col. 6, line 30).

With respect to claims 6 and 18, Salo et al. teaches that the plurality of selectable voltage sense and excitation current electrodes include the tip and ring electrodes of a plurality of sensing/pacing leads (leads 12, 14, and 15).

With respect to claims 8, 10, and 20, Hartley et al. discloses that the circuitry for demodulating the voltage sense signal samples generates a weighted average of the voltage sense signal samples (see col. 11, lines 1-33).

With respect to claim 9, Hartley et al. discloses that the excitation current waveform is output as a strobe made up of a specified number of excitation current waveform cycles with each strobe repeated at a specified strobing frequency (exciter 150 delivers an electrical excitation signal, such as a strobed sequence of current pulses; see col. 6, lines 17-30).

Response to Arguments

5. Applicant's arguments with respect to claims 1-10 and 12-20 have been considered but are not persuasive. Applicant argues that Hartley et al. fails to disclose further filtering the demodulated signal when no excitation current is supplied into the

ventilation band (see pages 9-10 of Response filed 5/23/06). However, as explained above, Hartley et al. discloses that the gain of the demodulator 415 may be increased during the noise sensing mode in order to provide for more sensitive noise detection (see col. 12, lines 25-33). In view of the disclosure that the demodulator 415 provides a voltage gain for the ventilation band during the noise sensing mode of operation, Examiner considers Hartley et al. to disclose filtering the voltage sensed signal when no excitation current is supplied into the ventilation band since such gain necessarily results in allowing only a particular range of voltages to be analyzed.

In addition, with respect to device claims 1-10 and 12, Examiner notes that the device of Hartley et al. has the capability of filtering voltage sense signals via demodulator 415 (see col. 11, lines 13-33) and bandpass filter 420 (see col. 12, line 50 - col. 13, line 13). A recitation of the intended use of the claimed invention (for example, the intended use of the circuitry for detecting noise when no excitation is supplied) must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Since the device of Hartley et al. is capable of filtering the voltage sense signals during normal operation, Examiner considers the device also capable of filtering such signals during the noise sensing mode of operation described at col. 12, lines 11-48.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole R. Kramer whose telephone number is 571-272-8792. The examiner can normally be reached on Monday through Friday, 8 a.m. to 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NRK
7/6/06

George Manual
Primary Examiner